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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/575,026	10/02/2006	Frans-Josef Meyer-Almes	BHC 03 1002	5952
35969 7590 01/20/2010 Barbara A. Shimeci Director, Patents & Licensing Bayer HealthCare LLC - Pharmaceuticals 555 White Plains Road, Third Floor Tarrytown, NY 10591				
EXAMINER				
TURK, NEIL N				
ART UNIT		PAPER NUMBER		
1797				
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/575,026

Applicant(s)

MEYER-ALMES ET AL.

Examiner

NEIL TURK

Art Unit

1797

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 10/27/09.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 10-29 is/are pending in the application.
- 4a) Of the above claim(s) 20-29 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 10-19 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 07 April 2006 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/GS/US)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

Remarks

This Office Action fully acknowledges Applicant's remarks filed on October 27th, 2009. Claims 10-29 are pending. Claims 20-29 have been withdrawn from consideration as being drawn to a non-elected invention.

Election/Restrictions

Newly submitted claims 20-29 are directed to an invention that is independent or distinct from the invention originally claimed for the following reasons: Newly submitted claims 20-29 lack the technical feature of claim 10 which comprises a modifying agent that is capable of changing the molecule from a first state to a second state, and instead, comprises a method of screening for a modifying agent that is capable of modifying a molecule in a first state to a second state.

Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claims 20-29 are withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 10-19 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 10 recites the limitation "the fluorescence lifetime", "the fluorescently labeled molecule", and "the molecule". **Claims 11-13** recite the limitation "the fluorescent dye". There is insufficient antecedent basis for these limitations in the claims.

Does Applicant intend to claim a sort of step involving labeling a molecule with a fluorescent dye before the measuring step of step (a)?

Further, in step (b), Examiner asserts that "the molecule" should read as "the fluorescently labeled molecule" so as to parallel that of step (a).

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 10-19 are rejected under 35 U.S.C. 102(b) as being anticipated by Burke et. al. (2001/0004522), hereafter Burke.

Burke discloses kinase activity measurement using fluorescence polarization (abstract). Burke discloses a method for detecting phosphorylated amino acids which allows for quantitative measurement of protein kinase and phosphatase activity (par. [0017], fig. 2, fig. 4).

Burke discloses that a competition assay may be performed, and the synthesis of the phosphorylated peptide during the reaction is detected by adding a high polarization complex to the reaction. The complex comprises a fluorescently labeled phosphopeptide bound to an antibody, and as the reaction mixture and complex are combined, the antibody will reach equilibrium between the phosphorylated amino acids from both sources. Burke discloses that as the antibody is released from the fluorescently labeled phosphopeptide, the polarization value goes down in proportion to the amount of phosphorylated amino acids made by the kinase reaction (par. [0038], Example 2, par. [0047]). Burke discloses that the method involves the steps of:

a) measuring the fluorescence polarization of a reporter molecule comprising a phosphorylated amino acid (molecule) and a fluorescence-emitting molecule (measuring the fluorescence lifetime of the fluorescently-labeled molecule in a first state)

b) adding an enzyme (modifying agent capable of changing the molecule from a first to a second state), wherein the enzyme comprises a kinase or phosphatase, and a substrate;

c) incubating the solution;

d) measuring the fluorescence polarization of the solution during step c) (measuring the fluorescence lifetime after contact with the modifying agent); and,

e) comparing the fluorescence polarization measurement of step a) with step d).

(see *Claims 6-11, col. 8*)

Burke further shows the competitive detection steps in figure 2 and measured results in figure 4 are shown, which demonstrate the shifts in polarization as antibody is added.

Burke further discloses that the fluorescent-emitting dyes such as fluorescein, coumarine, rhodamine, and others may be used (par. [0043]). Examiner asserts that use of such dyes as labels to the phosphorylated amino acid utilize a covalent bond therebetween, and further, the molecules which make up the covalent bond are said to comprise a spacer.

Response to Arguments

Applicant's arguments with respect to claims 1-9 have been considered but are moot in view of the new ground(s) of rejection, as discussed above. Further, claims 1-9 have been canceled. Newly added claims 10-19 have been rejected under new grounds as discussed above, under both 35 USC 112, 2nd paragraph, and 35 USC 102(b). Further, newly added claims 20-29 have been withdrawn from consideration as being drawn to a non-elected invention.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to NEIL TURK whose telephone number is (571)272-8914. The examiner can normally be reached on M-F, 9-630.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill Warden can be reached on 571-272-1267. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

NT

/Jill Warden/
Supervisory Patent Examiner, Art Unit 1797

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